

Message Text

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ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 IO-10 OES-05 L-03 CIAE-00 INR-07

NSAE-00 AID-05 EB-07 SNM-02 DEAE-00 COME-00 TRSE-00

OMB-01 DODE-00 SP-02 /061 W
----- 012801

P 291626Z AUG 75

FM AMEMBASSY BONN

TO SECSTATE WASHDC PRIORITY 2488

UNCLAS SECTION 01 OF 02 BONN 14164

E.O. 11652: N/A

TAGS: ETRD, TBIO, PINT, GW

SUBJECT: NEW GERMAN PHARMACEUTICAL REGULATIONS

REF: (A) STATE 248387, (B) BONN 19461 (C) BONN 134799

FOR FDA-DR. SCHMIDT MD, COMMISSIONER OF FDA

1. AFTER FIRST READING IN THE BUNDESTAG THE GOVERNMENT-SPONSORED BILL ON THE GERMAN DRUG REFORM WAS SENT TO THE RESPONSIBLE BUNDESTAG COMMITTEES ON JAN. 16, 1975. THE DELIBERATION OF THE BILL BY THE BUNDESTAG SUB-COMMITTEE IN CHARGE OF GERMAN DRUG REFORM WITHIN THE COMMITTEE FOR YOUTH, FAMILY AND HEALTH, ARE SCHEDULED TO BEGIN SEPT. 20, 1975.

2. IN GENERAL, THE BILL WHICH IS TO REPLACE THE 1961 DRUG LAW, AS AMENDED 1964, IS CONSIDERED BY THE FEDERAL GOVERNMENT ON THE NATIONAL LEVEL, AS ANOTHER CONTRIBUTION TO GERMAN CONSUMER PROTECTION BY ENSURING OPTIMAL DRUG SAFETY; ON THE INTERNATIONAL LEVEL, AS AN ESSENTIAL CONTRIBUTION TO THE ESTABLISHMENT OF A COMMON EUROPEAN DRUG LEGISLATION AND A COMMON EUROPEAN DRUG MARKET, AS WELL AS THE BASIS FOR TRANSFORMING INTO NATIONAL LAW, THE WORLD HEALTH ORGANIZATION (WHO) DIRECTIVE ABOUT THE BASIC RULES FOR THE MANUFACTURE OF PHARMACEUTICALS AND THEIR QUALITY ASSURANCE.

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3. IN DETAIL, THE HIGHLIGHTS OF THE BILL ARE:

A. THE PRESENT REGISTRATION REQUIREMENT FOR PREPARED DRUGS (PATENT MEDICINES WILL BE CHANGED TO A LICENSING REQUIREMENT. THUS, IN THE FUTURE, PREPARED DRUGS PRODUCED IN FEDREP CAN BE MARKETED, AND FOREIGN PRODUCTS CAN BE IMPORTED ONLY, IF THEY HAVE BEEN LICENSED FOR SALE BY THE FEDERAL HEALTH OFFICE AT BERLIN. IN ADDITION TO THE DATA WHICH HAD TO BE SUBMITTED SO FAR WITH THE APPLICATION FOR REGISTRATION OF PREPARED DRUGS, THE LICENSE APPLICATION MUST INCLUDE PROOF THAT THE PREPARED DRUGS ARE OF THE ASSURED QUALITY, THAT THEY ARE EFFECTIVE IN THE FIELD OF APPLICATION INDICATED BY THE MANUFACTURER, THAT THEY ARE SAFE, AND ARE NOT MISBRANDED. FOR DRUGS WHICH ARE ALREADY ON THE MARKET, IT IS PROPOSED THAT THEY WILL GRADUALLY BECOME SUBJECT TO A REVIEW BY A SPECIAL PANEL, WHICH IS TO BE ATTACHED TO THE FEDERAL HEALTH OFFICE.

THE ABOVE REQUIREMENTS WILL ALSO BE APPLICABLE TO NATURAL DRUGS.

IT IS FURTHER PROVIDED THAT THE LICENSE APPLICATION OF AN IMPORTER FOR PREPARED DRUGS OF FOREIGN MANUFACTURE, MUST INCLUDE PROOF THAT THE DRUGS HAVE BEEN MANUFACTURED ACCORDING TO WHO STANDARDS. THIS MAY BE ACCOMPLISHED IN FORM OF A CERTIFICATE WHICH IS TO BE ISSUED BY THE DRUG CONTROL AGENCY IN THE COUNTRY OF MANUFACTURE, PROVIDED THERE IS MUTUAL RECOGNITION OF SUCH CERTIFICATES.

B. THE EXISTING PRESCRIPTION REQUIREMENTS ARE TO BE TIGHTENED IN SUCH A MANNER, SO THAT IN CASES OF DRUG ABUSE, OVER-THE-COUNTER-DRUGS (OTC) CAN BECOME SUBJECT TO PRESCRIPTION REQUIREMENTS.

C. PRODUCTION CONTROL AND QUALITY CONTROL OF PREPARED DRUGS ARE TO BE INTENSIFIED IN ORDER TO MEET THE RULES OF GOOD MANUFACTURING PRACTICE (GMP) ESTABLISHED BY THE WHO.

D. AS ANOTHER VEHICLE OF DRUG SAFETY, THE FOLLOWING ADDITIONAL INFORMATION FOR THE CONSUMER MUST BE SHOWN ON THE LABELS OF PREPARED DRUGS

(1) COUNTERINDICATIONS, SIDE EFFECTS, EFFECTS ON OTHER DRUGS, AND
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(2) WARNINGS IN CASES WHERE THE DRUGS MAY IMPAIR THE REACTIONS IN DRIVING AND AT WORK, OR WHEN THEY SHOULD NOT BE TAKEN DURING PREGNANCY,

(3) EXPIRATION DATES.

THE SAME INFORMATION MUST ALSO BE FURNISHED IN DRUG ADVERTISING.

E. A CENTRAL INFORMATION SERVICE WILL BE ESTABLISHED

WITH THE FEDERAL HEALTH OFFICE WHICH WILL SERVE FOR EX-
CHANGE AND EVALUATION OF INFORMATION OF DRUG HAZARDS, AD-
VERSE SIDE EFFECTS IN PARTICULAR, AND MISBRANDINGS.
ACCORDING TO A SPECIAL ALARM-PLAN, DRUGS MAY BE

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INFO OCT-01 EUR-12 ISO-00 IO-10 OES-05 L-03 CIAE-00 INR-07

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RECALLED FROM THE MARKET, AS

SOON AS DANGEROUS QUALITIES BECOME APPARENT.

F. EVEN THOUGH ALL CARE IS TAKEN TO ENSURE THE PRODUC-
TION OF SAFE DRUGS, INJURY MAY STILL OCCUR FOR WHICH NO
MANUFACTURER IS AT FAULT. IN THOSE CASES THE PERSONS
INJURED WILL BE ENTITLED TO AN ADEQUATE COMPENSATION
WHICH IS TO BE PAID FROM A FUND TO WHICH GERMAN PHARMA-
CEUTICAL MANUFACTURERS AS ITS MEMBERS MUST CONTRIBUTE.

G. SINCE DRUG SAFETY REQUIRES COMPREHENSIVE TESTING,
INCLUDING CLINICAL TESTING, THE USE OF HUMAN SUBJECTS
FOR SUCH PURPOSES IS PERMISSABLE ONLY IF SPECIAL LEGALLY
PRESCRIBED PEREQUISITES ARE MET. THE LATTER WILL EN-
SURE THAT SUCH PERSONS WHO MAKE THEMSELVES AVAILABLE FOR
CLINICAL TESTING WILL BE PROTECTED TO THE GREATEST POS-
SIBLE EXTENT.

4. THE EMBASSY WILL REPORT AGAIN WHEN THE FINAL VERSION
OF THE BILL IS AVAILABLE, I.E. AFTER SECOND AND

THIRD READING BY THE BUNDESTAG WHICH IS EXPECTED FOR
SPRING 1976. AFTER THE BILL IS SIGNED INTO LAW A ONE-
YEAR GRACE PERIOD IS PROVIDED DURING WHICH THE INDUSTRY
CAN ADAPT ITSELF TO THE NEW PROVISIONS.

5. PARLIAMENTARIANS OF THE BUNDESTAG SUBCOMMITTEE
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DEALING WITH THE GERMAN DRUG REFORM WILL VISIT THE FDA
SEP. 2 (REF C) IN LINE WITH A STUDY TOUR OF US DRUG
CONTROL LEGISLATION. THE GROUP IS ACCOMPANIED BY
MINISTERIALRAT DR. FEIDEN FROM THE FEDERAL GERMAN HEALTH
MINISTRY, ONE OF THE OFFICIALS WHO ARE RESPONSIBLE FOR
THE PREPARATION OF THE BILL. FDA MAY WISH TO TAKE THE
OPPORTUNITY TO DISCUSS DETAILS OF THE BILL DIRECTLY
WITH THE OFFICIAL. WE UNDERSTAND THAT DR. FEIDEN WILL
RAISE WITH FDA THE QUESTION ON THE MUTUAL RECOGNITION
OF CERTIFICATES (SEE UNDER 3A ABOVE).

6. COPY OF THE BILL WILL BE SENT TO DR. SCHMIDT BY RE-
GISTERED AIRMAIL.
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